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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/615,213	07/07/2003	William E. Bay	1946/1G906-US2	8060

7590 12/05/2006

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EXAMINER	
DESAI, RITA J	

ART UNIT	PAPER NUMBER
1625	

DATE MAILED: 12/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/615,213	BAY ET AL.	
	Examiner	Art Unit	
	Rita J. Desai	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29 and 62-66* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29, 62-66* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

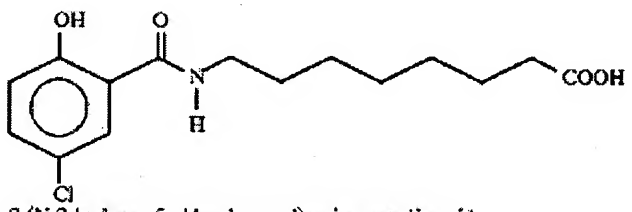
Claims 29, 62-66 are pending.

Claims 1-28 and 30-61 have been cancelled.

The rejection of the claims 29, 62-66 under 35 USC 103 over WO 96/30036 in view of WO 97/36480, US 5773647, WO 95/28838 Leone –Bay et al , and US 4757066 Shiokari et al still stands.

Applicants were right the previous rejection was in view of all the documents previously cited. Applicants argue the WO 96/30036 and WO95/28838 does not disclose the 5-CNAC compound. It may be so. However it does disclose several other delivery agents similar to it. See for example XI, XIX, XX, XXVII, XXVIII on pages 5-8 and 51, 52 of the '036 document.

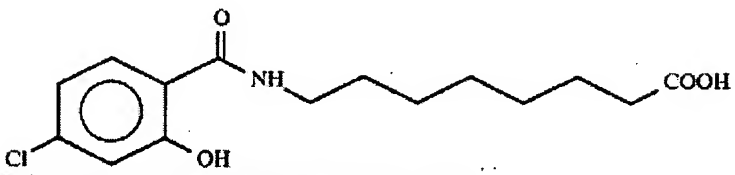
US 577647 disclose the 5-CNAC as a delivery agent. See compound



8-(N-2-hydroxy-5-chlorobenzoyl)aminocaprylic acid

compound 109.

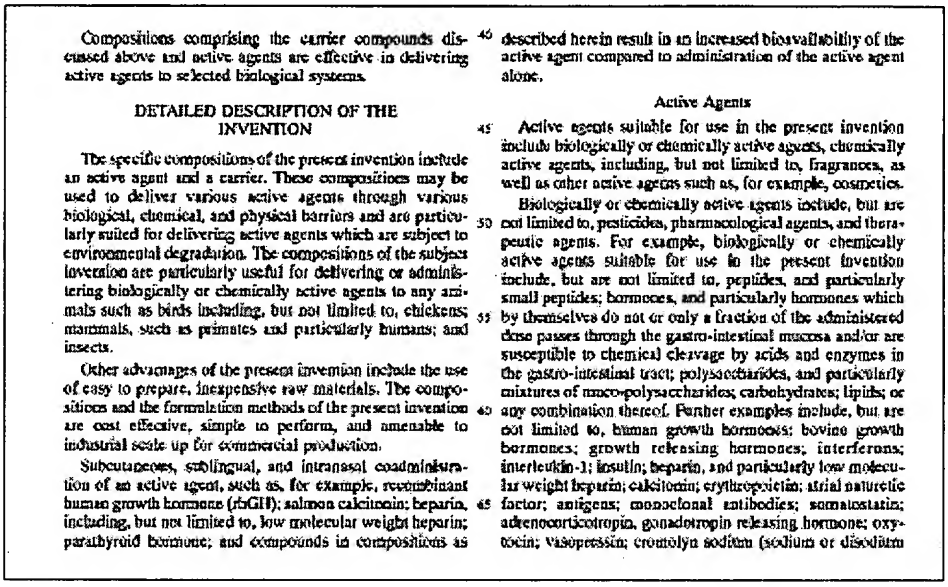
Another similar compounds positional isomer is also



8-(2-hydroxy-4-chlorobenzoyl)aminocaprylic acid

shown.

The reference on columns 47 and 48 clearly disclose using them as delivery agents to deliver active agents through various biological barriers to humans , birds, chickens, insects and so on.



Compositions comprising the carrier compounds discussed above and active agents are effective in delivering active agents to selected biological systems.

DETAILED DESCRIPTION OF THE INVENTION

The specific compositions of the present invention include an active agent and a carrier. These compositions may be used to deliver various active agents through various biological, chemical, and physical barriers and are particularly suited for delivering active agents which are subject to environmental degradation. The compositions of the subject invention are particularly useful for delivering or administering biologically or chemically active agents to any animals such as birds including, but not limited to, chickens; mammals, such as primates and particularly humans; and insects.

Other advantages of the present invention include the use of easy to prepare, inexpensive raw materials. The compositions and the formulation methods of the present invention are cost effective, simple to perform, and amenable to industrial scale up for commercial production.

Subcutaneous, sublingual, and intranasal coadministration of an active agent, such as, for example, recombinant human growth hormone (rhGH); salmon calcitonin; heparin, including, but not limited to, low molecular weight heparin; parathyroid hormone; and compounds in compositions as described herein result in an increased bioavailability of the active agent compared to administration of the active agent alone.

Active Agents

Active agents suitable for use in the present invention include biologically or chemically active agents, chemically active agents, including, but not limited to, fragrances, as well as other active agents such as, for example, cosmetics.

Biologically or chemically active agents include, but are not limited to, pesticides, pharmacological agents, and therapeutic agents. For example, biologically or chemically active agents suitable for use in the present invention include, but are not limited to, peptides, and particularly small peptides; hormones, and particularly hormones which by themselves do not or only a fraction of the administered dose passes through the gastro-intestinal mucosa and/or are susceptible to chemical cleavage by acids and enzymes in the gastro-intestinal tract; polysaccharides, and particularly mixtures of muco-polysaccharides; carbohydrates; lipids; or any combination thereof. Further examples include, but are not limited to, human growth hormones; bovine growth hormones; growth releasing hormones; interferons; interleukin-1; insulin; heparin, and particularly low molecular weight heparin; calcitonin; erythropoietin; atrial naturetic factor; antigens; monoclonal antibodies; somatostatin; adrenocorticotropin, gonadotropin releasing hormone; oxytocin; vasopressin; cromolyn sodium (sodium or disodium

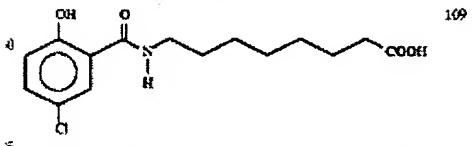
The compounds are thus used for a method of delivering active agents and reads directly on the limitation of claim 29, as it clearly discloses the active agents can be hormones. (Calcitin falls within the scope of hormones).

Even though applicants have limited their claims to atleast 50 % by weight , it does not bear any patentable weight as the reference may inherently have that limitation and also it does not have any unexpected results.

It is correct that the reference do not specifically state “di” sodium salts , however they do specifically say salts. With 2 hydroxy groups it is obvious it would form a disodium salt.

The reference 5,773,647 does recite or a salt thereof, which would encompass the disodium salt.

What is claimed is:
1. A composition comprising:
(A) at least one active agent; and
(B) a compound having the following formula



or a salt thereof.
2. A composition as defined in claim 1, wherein said

Claim 11 of the reference teaches the unit dosages too.

Thus the rejection still stands.

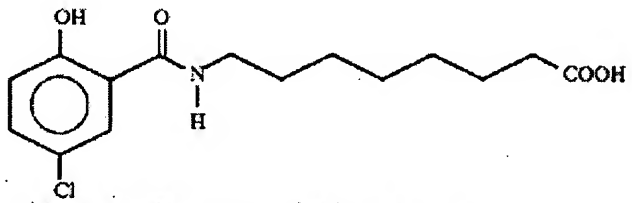
The above rejection can also be made on just the US 5,773,647 alone:-

Claims 29, 62-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,773,647 alone.

Applicants claims are drawn to a method of delivering salmon calcitonin with 5-CNAC disodium salt and also drawn to pharmaceutical compositions of the same and also other active ingredients.

Determination of the scope and content of the prior art (MPEP §2141.01)

US 5, 773,647 teaches the 5-CNAC and its salts as a delivery agent to deliver hormones etc. See the above arguments. See compound 109



8-(N-2-hydroxy-5-chlorobenzoyl)aminocaprylic acid

and the claims which recites its salts also see page 44 wherein the active agent is calcitonin.

The inject able solution is brought back to pH 7.2 to 8.0 which is basic, (see page 46 '*The delivery agents were reconstituted with distilled water and adjusted to pH 7.2-8.0 with either aqueous hydrochloric acid or aqueous sodium hydroxide. A stock solution of sCT was prepared by dissolving sCT*") hence it is obvious the solution would have the Na salts, and as there are 2 hydrozyable OH's it would be obvious it would form a di sodium salt.

The rejection of claims 1, 5, 9, 13-22, 29-58 and 64 (now claims 29, 62-66) under 35 USC 112 first paragraph still stands. Applicants have amended the claim to just 5-CNAC however claims 62-66 are not limited to just the salmon calcitonin (sCT). It is drawn to a pharmaceutical composition with any active agent. That too a pharmaceutical composition.

There is no written description that these have any "pharmaceutical " activity not is there any written description of what these active agents are., vitamins , growth hormones, interferons, human recombinant insulin , analogs , fragments and so on. Applicants do not have any description or even a partial structure of what is encompassed by these groups.

Applicants definition of these groups are more to the function.

Analogs, fragments mimetics, derivatives could be any chemical compound.

Claim 66 has disintegrant, lubricant, plasticizer, colorant, and so on. They do not have a description and definition of what is encompassed by the term.

In re Curtis 69 USPQ2d 1274.

Conclusion

Claims 29, 62-66 are rejected.

This action is not made final as examiner has reformulated the rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita J. Desai whose telephone number is 571-272-0684. The examiner can normally be reached on Monday - Friday, flex time..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Rita J. Desai
Primary Examiner
Art Unit 1625

R.D.
November 28, 2006